

RA 8/24/15
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:)	Premanufacture Notice Number:
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[)	P-15-154
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EPA SANITIZED

Consent Order and Determinations Supporting Consent Order

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PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN"), P-15-154, [

submitted by [] ("the Company"). The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these requires the Company to:

(a) submit to EPA certain toxicity and physical/ chemical and environmental fate testing relevant to the hazard and risk assessment of the fluorinated portion of the former PMN substance and the current PMN substance, P-15-154 as governed by the attached Consent Order;

- (b) report annually and comply with the impurity content of all the [] and impurities with carbon chain lengths greater than [] by analyzing representative samples; and
- (c) maintain certain records.

Although a Consent Order for Contract Manufacturer is not attached to extend these requirements to an identified Contract Manufacturer, the Company may use a Contract Manufacturer to manufacture these substances in the future. The Consent Order establishes the requirements for the Company if a Contract Manufacturer manufactures the PMN substance. The Company must submit the Contract Manufacturer identity and other manufacturing process and exposure and release information concerning the Contract Manufacturer and then this Consent Order could be modified upon approval by EPA. The Contract Manufacturer would be required to keep records of quantities manufactured, but the Company must submit to EPA the required testing.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): company identity, specific chemical identities, physical form, production volumes, processing, and use information, and other information

Chemical Identities:

Specific: P-15-154: []

Generic Name: Fluoroalkyl acrylate copolymer

Use:

Specific: []

Generic use: Textile Treatment

Production Volume: [] kgs []

Test Data Submitted with PMN: Oral LD50, Skin Irritation Studies (2), and Eye Irritation Study.

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects and Fate Summary: EPA has concerns for potential incineration or other potential degradation products, by products, unreacted material, and low molecular weight species of the PMN substance. EPA also has concerns that the PMN polymeric substances themselves under some conditions of use-- particularly non-industrial, commercial, or consumer use-- could cause lung effects, based on limited data on some [] compounds.

EPA has concerns for the potential degradation of these polymers and for the subsequent [perfluorinated products]. The PMN substance degrades to []. Based on information submitted to EPA during the PMN review period, these substances have some [higher homologue or chain length perfluorinated] impurities.

To further document the actual contamination and efforts to reduce impurity levels, the Company has agreed to limits in the starting materials and report the various fluorinated [] impurities and [] periodically. [] has reported the [] impurities and []

[] in compliance with previous Consent Orders. [] no longer makes the [] products at the same facilities as the PMN substance. EPA strongly encourages the continued effort to maintain these low levels of [] impurities and to make improvements until there are no longer any [] in these products.

Perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. Preliminary evidence suggests that under some other conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic ("PBT") to people, wild mammals, and birds based on data on analog chemicals, including PFOA. The potential [] degradants for the PMN substance include [].

The analog PFOA is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples. Toxicity studies on PFOA indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the EPA regulatory docket at EPA-HQ-OPPT-2003-0012. Additional information about PFOA and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226)*.

Limited toxicological, ecological, and related fate data now exist on [] and some of the []-derived polymers and other related substances; see the PMN docket for these specific PMNs.

There are limited pharmacokinetics studies on [] in the rat and the monkey. These studies indicate that the serum half-life is less than 24 hours in monkeys, which is considerably less than the half-life of PFOA in monkeys and humans. The half-life of PFOA in monkeys is 20.9 days in female monkeys, 32.6 days in male monkeys, and 4.4 years in humans. These data and assessments support the assessment of reduced bioaccumulation of [] relative to PFOA.

In addition, EPA has reviewed a Combined Repeated-Dose Toxicity Study with Reproduction/Developmental Screening Test, (OECD 422) in rats for [] and the [] conducted for another company and submitted to EPA. EPA's review of these subchronic and reproductive data on [] and the [] concluded that for [] no reproductive effects were seen at any dose. Dose levels were 50, 150, and 450/300 mg/kg/day (450 was reduced to 300 in the study on day 4 because of toxicity). However, systemic effects—primarily liver effects—were seen. EPA's review places the No-Adverse Effect Level or NOAEL for [] at 50 mg/kg/day.

For the [], the doses were 25, 75, and 225 mg/kg/day. For systemic effects, there was no NOAEL achieved with the Lowest-Adverse Effect level (LOAEL) at 25 mg/kg/day. For reproductive or developmental effects, the NOAEL is 75 mg/kg/day and LOAEL is 225 mg/kg/day.

In 2006, another company submitted a 90-day oral repeated dose toxicity study (OECD 408) on []. Dose levels for this study were 0 (vehicle control), 10, 50, and 200 mg/kg/day and were based on the previously described Combined Study (OECD 422). EPA's review sets the Lowest- Effect or Lowest-Adverse Effect Level (LOEL or LOAEL) at 10 mg/kg/day, based on the body weight gain being lower in all treated groups of males. There was treatment-related toxicity in the liver and the red blood cell system (anemia) in males at 200 mg/kg/day. There was also increased peroxisomal beta oxidation activity at this dose level. Hepatotoxicity and peroxisomal beta oxidation activity have also been seen in

studies on PFOA. The significance of the finding of a benign brain tumor (astrocytoma) in one male rat in the high dose group is not clear. It is not the type of tumor normally associated with PFOA-type compounds, is not a rare tumor, and may be incidental. Abnormal histopathology was observed in the testes (2 males) and epididymides (1 male) at 200 mg/kg/day and is a sign of concern for male reproductive toxicity. Further testing should investigate male reproductive effects. From this study, the potential for immunotoxic effects is low. There have been some studies showing immunotoxic effects from PFOA. Any investigation of immunotoxic effects should await the corroborative testing now being conducted by the EPA Office of Research and Development. There were no clinical signs of neurotoxicity and there were no treatment-related effects in the functional observation battery or motor behavior in the study.

Another 90-day study has been submitted to EPA on []. EPA review of that study concluded that blood and liver effects were seen at the highest dose. This study had doses comparable with the other studies. Another 90-day study has been submitted to EPA on []. EPA review of that study concluded that blood and liver effects were seen at the highest dose. This study had doses comparable with the other studies.

A one-generation reproduction/developmental toxicity study in mice on the [] was submitted to the Agency. In this study, pregnant mice were administered the test substance via gavage during gestation days 6-18. The NOAEL for maternal toxicity was 175 mg/kg/day (the highest dose tested). Signs of developmental toxicity were observed at 175 mg/kg/day on the postnatal day 1 and consisted of increases in the number of stillborn pups and pup deaths, reductions in the average pup body weight per litter with a pup with lenticular opacity. The NOAEL for developmental toxicity is 35 mg/kg/day.

A Chronic Toxicity, Carcinogenicity study was submitted in 2011. Doses were 2.5, 15, and 100 mg/kg/day for males and 5, 30, and 200 mg/kg/day for females. EPA review determined that no chronic toxicity or carcinogenicity effects were seen in the two lower doses. Due to limitations in the study no determination could be made for the highest doses.

These and other data to date also indicate a different and less toxic profile for [], a potential environmental degradant of the PMN substance, than for PFOA. Based on: 1) the persistence of [], 2) potential intermediate fate products, and 3) the likelihood that these substances may be used as major substitutes for some uses of PFOA, EPA believes that information is needed on the toxicity of [] and possibly other environmental degradants, and on the fate and physical/chemical properties of [] and []-derived polymers in the environment.

Additional relevant testing on analogous [] substances will be developed by the National Toxicology Program or NTP in the so-called Perfluoro Class Study.

Environmental Effects Summary: EPA has a low concern for the intact PMN substance P-15-154 based structure activity relationships and data on []. EPA does not expect a significant environmental risk from the intact polymers. However, there is concern for possible environmental effects of the potential persistent degradation products of the PMN substance, including [], particularly in wild mammals and birds, and possibly to the reproductive capacity of other species. The analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of wildlife species including marine mammals. It is toxic to mammalian and other species. The presence in the environment and the toxicological properties of PFOA continue to be investigated.

EPA believes development of additional data is warranted. The Company has agreed to conduct,

and the Consent Order requires the Company to conduct, a Fish Full Life Cycle study test and a Fish Reproduction study on a salt of [].

Exposure and Environmental Release Summary: Thermal and simulated incineration testing exists on some related polymers. This testing indicates that incomplete incineration products are formed at lower incineration temperatures. EPA does not believe further thermal and simulated incineration testing is warranted for these polymers.

Modified Zahn-Wellens biodegradation tests have been conducted on some related polymers. In addition, other fate tests have been conducted that show that analogous polymers degrade. EPA believes that additional data on the fate and transport of the PMN substance is warranted. EPA is requiring the Company to test the polymers, P-13-649 and P-13-679 as representative test substances in physical/chemical and environmental fate tests as listed below. EPA believes that P-13-649 and P-15-154 are similar polymers and thus the results of the following tests on P-13-649 will be reasonably representative for P-15-154.

Physical/Chemical Property Testing	OPPTS or OECD Guideline
Hydrolysis as a function of pH	OCSPP 835.2130, OECD 111

Environmental Fate Testing	OPPTS or OECD Guideline
Modified Semi-Continuous Activated Sludge (SCAS) or Zahn-Wellens with Analysis for degradation products	OCSPP 835.5045, OCSPP 835. 3210, OECD 302A or OCSPP 835.3200, OECD 302B
Indirect Photolysis Screening Test	OPPTS 835.5270

The fluorinated starting materials for the PMN substance will be imported.

For processing of the PMN substance into a polymer, the PMN substance will be processed at

[]. Presently, all releases are []. Environmental

via incineration is expected. The PMN substance is [] in solution and diluted/mixed down to [] in solution. The new chemical is intended to be used in [] settings only.

Use of the PMN substance: EPA expects that there is potential for dermal exposure to workers, but does not expect inhalation exposure to workers from processing or use at industrial sites. During use for P-15-154, EPA expects releases to air from incineration. During use for P-15-154 as a [], the substance may be released to water, incineration, or landfill. EPA estimates that the substances could be used at [] sites for [] days per year.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

- (a) EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substance and potential degradation products. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance and potential degradation products.
- (b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture (which includes import), processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.
- (c) In light of the estimated production volume of, and human exposure to, the PMN substance and potential degradation products, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that

the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and potential degradation products.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

1. Information on inhalation toxicology if the substances were to be sprayed by non-industrial, commercial or consumer applicants. This could include a 90-day inhalation study in rats with a 60-day holding period (OPPTS Guideline 870.3465 or OECD 413) or other relevant information.

2. The following physical/chemical properties and fate and transport tests (also discussed previously in this preamble):

Physical/Chemical Property Testing	OPPTS or OECD Guideline
UV visible absorption	OPPTS 830.7050



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the following chemical substance [

] P-15-154 (the "PMN substance") submitted by [] ("the

Company") except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing of the PMN substance is exempt from the requirements of this Order (except the requirements in the Record keeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate record keeping as required in the Record keeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR

Environmental Fate Testing	OPPTS or OECD Guideline
Aerobic and Anaerobic transformations in Aquatic Sediment Systems	OECD 308
Direct Photolysis in Water	OPPTS 835.2210
Phototransformation Chemicals on Soil Surfaces	OECD Jan. 2002 Draft
Simulation test-Aerobic Sewage Treatment (Activated Sludge Units)	OECD 303A
Anaerobic biodegradability of organic compounds in digested sludge	OECD 311

Because of the physical/chemical properties of these substances, some modifications of the protocols may be necessary. These modifications will be agreed upon by EPA and the Company.

720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activities by the Company involving the PMN substance are exempt as “solely for export” even if some amount of the PMN substance are later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development (“R&D”). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when they are produced, without separate commercial intent, only as a “byproduct” as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when they are manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which they are a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when they are imported as part of an “article” as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption (TME) under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption (LVE) or Low Release and Exposure Exemption (LoREX) under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

**II. TERMS OF MANUFACTURE, PROCESSING,
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL
PENDING SUBMISSION AND EVALUATION
OF INFORMATION**

PROHIBITION

The Company is prohibited from manufacturing the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Restriction. The Company shall not manufacture the PMN substance, P-15-154 unless the [] starting material and the []

[] intermediate material is in compliance with and does not exceed the limits specified in Table 1 and Table 2. The Company shall analyze the products containing the PMN substance for the analytes specified in Table 3 upon initial commencement of manufacture, and for any of the PMN substance manufactured since the last required analysis at least annually analyze and report thereafter, until one

manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company shall continue to report these impurity levels to EPA annually, in a cycle complementary to the [].

In addition to the reporting for the products containing the PMN substance themselves, the Company shall, for the [] starting material, annually report (1) the average values and the range of values, including outlying data, for the routine analysis for the analytes specified in Table 1 and (2) the results of the quarterly analyses for the analyte specified in Table 2.

TABLE 1:

TO BE ROUTINELY ANALYZED IN [] STARTING MATERIAL

Analyte	CAS Number	Limit in [C6 Iodide]
[]	[]	[] minimum
[] []	[] []	[] (combined)

TABLE 2:

TO BE ANALYZED AT LEAST QUARTERLY IN [] INTERMEDIATE MATERIAL

Analyte	CAS Number	Limit in []
[]	[]	[]

TABLE 3:

TO BE ROUTINELY ANALYZED AT START-UP AND AT LEAST ANNUALLY THEREAFTER IN THE PMN substance OR PRODUCTS CONTAINING THE PMN substance

Analyte	CAS Number	Limit in [PMN substance or products containing the PMN substance]

year after the date of the last joint manufacture or processing of a product that contains [] products at the facility. The Company shall report annually to the Agency the levels of impurities [] associated with the PMN substance, P-15-154 manufactured by the Company, as specified below. For routine analysis, the Company shall analyze the starting material, [] for the following analytes shown in Table 1 below: []

[]. The Company will also quarterly analyze the intermediate material, []

[], for the analyte [] shown in Table 2, below. The Company shall make its best effort to minimize [] and to seek to eliminate them.

(b) Analysis and Reporting. The Company shall analyze representative samples of products containing the PMN substance, P-15-154 manufactured by the Company to determine compliance with the requirements in paragraph (a). The Company shall also analyze the products containing the PMN substance at each manufacturing facility both (1) at the initial commencement of non-exempt manufacture of the PMN substance at that facility, and (2) at least annually thereafter during every year in which the PMN substance are manufactured at that facility or imported. If any new facility of manufacture is added or if the process of manufacture of the PMN substance are significantly altered, then the products containing the PMN substance or corresponding products containing the PMN substance must be analyzed at commencement, and annually thereafter as set forth above. If the PMN substance are imported, the Company shall obtain from the foreign manufacturer written documentation to certify that representative samples of the imported form of the PMN substance or corresponding products containing the PMN substance have been analyzed, consistent with the requirements of this paragraph (b), and determined to comply with the requirements of paragraph (a). The Company shall report the above analysis to EPA at initial commencement of manufacture and again if any new

[]	[]	[]
[]	[]	[]

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) Contract Manufacturer. Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture or import the PMN substance according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the

total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (to be attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture of the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture

the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substance only upon written notification from the Agency.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance present a substantial risk of injury to health or the environment, which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for these substances and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsca8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

- (1) The date when the study is scheduled to commence;
- (2) The name and address of the laboratory which will conduct the study;
- (3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,
- (4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
Room 7117B
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review

(submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. (i) The Company is prohibited from manufacturing (including import) or causing another person (including a Contract Manufacturer) to manufacture the PMN substance, P-15-154 and the six PMN substances P-13-646, 647, 648, 649, 678, and 679 beyond the aggregate production volumes as specified below.

<u>Production Volume</u>	<u>Study</u>	<u>Guidelines</u>
<u>Tier 1</u>		
[] kgs	Modified SCAS for Insoluble and Volatile Chemicals, with analysis for degradation products or Zahn-Wellens inherent biodegradation test, w/analysis for degradation products	OPPTS 835.5045, OECD 302A OPPTS 835.3200, OECD 302B
<u>Tier 2</u>		
[] kgs	Hydrolysis as a Function of pH and temperature Indirect Photolysis Fish Life-Cycle Toxicity	OECD 111, OPPTS 835.2130 OPPTS 835.5270 OPPTS 850.1500
<u>Tier 3</u>		
[] kgs	Fish Short-Term Reproduction Assay	OECD 229, OPPTS 890.1350

(ii) The test substances for the Physical/Chemical and fate tests shall be the PMN substances P-13-649 and P-13-679. The test substance for the ecotoxicity fish studies shall be []. Chemical composition of the test substance shall be verified and a certificate

of analysis submitted..

(iii) Chemical composition of the test substance must be fully characterized. For polymers, characterization includes all information required on pages 5 and 6 of the PMN form (i.e. EPA Form 7710-25), except that data on residuals are only required for fluorinated substances. Although EPA understands that complete mass balance may not be achievable for the specified analytes, the Company shall attempt mass balance to the greatest extent practicable. EPA prefers that the Company test the commercial substance.

(iv) The Company must test for the following analytes in the Biodegradation Test (OECD 302A, and OECD 302B) : [

].

(v) Because the environmental fate pathway for photolysis may be different than for biodegradation, the Company must test for the following analytes in the photolysis test: identify the major fluorinated fragments and volatiles including: [

].

(vi) For the hydrolysis test, the company must test for the analyte, [

]

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA prior to exceeding the

applicable production limit. The final report and data must be submitted as a support document for the PMN substances, using the procedure set out in 40 CFR 720.40. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test

report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c) and (e), and shall submit the report and data to EPA with a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture of the PMN substances beyond the applicable

production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing,

manufacture, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substances, unless either:

(A) within 2 weeks from receipt of the notice, the Company complies with such requirements as EPA's notice specifies; or

(B) within 4 weeks from receipt of the notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part IV. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that any of the PMN substances may present a risk of injury to human health or the environment (or is

so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS") for those PMN substances, as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substances are reintroduced into the workplace.

(b) The Company must ensure that any Contract Manufacturers (as described in paragraph (b) of the Manufacturing section of this Order), persons who will receive the PMN substances from the Company, or who have received the PMN substances from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(1) of this Order, are exempt from all the requirements in this

Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other record keeping requirements in this Record keeping section;

(2) Records documenting compliance with the Chemical Synthesis and Composition section of this Order, including the results from analyzing representative samples of these substances.

(3) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(5) Records documenting the address of all sites of manufacture, import, processing, and use;

(6) Copies of material safety data sheets required by the Risk Notification section of this Order;

(7) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(8) The Company shall keep a copy of this Order at each of its sites where the PMN substances

are manufactured, processed, or used.

(b) Applicability. The provisions of this Recordkeeping section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012**.

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the

PMN substances and may reasonably be exposed to the PMN substances;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(v) Records required by the Record keeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under

this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit new PMNs to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit new PMNs to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN

substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances are manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date and time of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date and time of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order

effective as of the date and time of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed

therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section S(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

4 May 2015
Date

Maria J. Doa
Maria J. Doa, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

5/14/15
Date

Name

Title:

Company: [

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance (see TSCA s. 3(2)) described in the Premanufacture notice submitted by the Company relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

Company (Transferor)

PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____ ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

3. Confidential Business Information. The Successor in Interest hereby:

____ reasserts,

____ relinquishes, or

____ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

**TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER**

**NOTICE OF TRANSFER
(continued)**

Company (Transferor)

PMN Number

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

**TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER**

**NOTICE OF TRANSFER
(continued)**

Successor's Technical Contact

Address

City, State, Zip Code

Phone